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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Xavier Billot

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EXAMINER

BASQUILL, SEAN M

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,736	Applicant(s) BILLOT ET AL.	
	Examiner Sean Basquill	Art Unit 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>16 Mar 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. The examiner acknowledges that in the office action sent to applicants 22 May 2008, the examiner failed to include Claim 26 in Group II drawn to Claims 17-25 encompassing a compound and compositions for treating eye diseases. In a telephone conversation on 22 July 2008, the examiner explained the oversight and confirmed that Claim 26 would be examined with the remaining claims drawn to the compositions for treating eye diseases.

2. Applicant's election with traverse of a compound and compositions for treating eye diseases, Claims 17-26, in the reply filed on 19 June 2008 is acknowledged. The traversal is on the ground(s) that a technical feature unites the inventions as claimed. This is not found persuasive because while it is true that the two inventions as claimed share a technical feature, there is no unity of invention as required by MPEP 1893.03(d) because there is no general inventive concept owing to the lack of *special* technical feature within the meaning of 37 C.F.R. 1.475, as outlined in the previous office action.

The requirement is still deemed proper and is therefore made FINAL.

3. The examiner also notes the applicants election of the compound described in Example 7 found on page 43 of the specification as the species reading on the instant claims 17-26 for purposes of searching prior art.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicants are hereby granted the

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effective filing date of U.S. Provisional Applications 60/386,499 (June 6, 2002), 60/460,134 (April 3, 2003), and International Application PCT/CA03/00838 (June 2, 2003).

Information Disclosure Statement

5. The information disclosure statement filed 16 March 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Specifically, no copy of the WO00/38667 International Application publication has been provided with the IDS; a copy of an international search report is attached to the publication cover page, but no copy of the application publication has been included. Additionally, no translation of JP2000-1472 or Belgian Patent 672,205 has been provided. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

6. Claims 20 and 21 are objected to because of the following informalities: while the instant claims refer to the treatment of “hypertension,” no support can be found in the disclosure as to the instant claimed compound having any effect on vascular hypertension, as “hypertension” is ordinarily interpreted to mean by one of ordinary skill in the art. However, a claim to the treatment of “ocular hypertension” would certainly fall within the scope of the present disclosure. Appropriate correction is required.

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7. Claim 22 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. By referring to the multiple dependent claim 21, and then further incorporating multiple dependent language in an attempt to describe the second active ingredient, the instant claim 22 is improperly multiply dependent. See MPEP § 608.01(n). Accordingly, the claim 22 has not been further treated on the merits.

8. Claim 25 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. By referring to the multiple dependent claim 24, and then further incorporating multiple dependent language in an attempt to describe the second active ingredient, the instant claim 25 is improperly multiply dependent. See MPEP § 608.01(n). Accordingly, the claim 25 not been further treated on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 20 and 23 provide for the use of a compound of Formula I, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 20 and 23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a

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process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. *See Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967), and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 20-25 recite or depend on the limitation " the compound as defined in any one of Claims 1-10." Because Claims 1-16 have been withdrawn from examination, there is insufficient antecedent basis for this limitation in the claim. The examiner suggests redrafting the instant claims to reflect "the compound as defined in Claim 17" as a way of overcoming this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
11. Claims 17-19, 21, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over International Application Publication WO01/46140 (hereinafter "Cameron"), in view of International Application Publication WO02/24647 (hereinafter "Maruyama").
12. Cameron discloses a series of E₂ prostaglandins for the prevention of bone loss, particularly agonists of the EP₄ subtype receptor nearly identical to the compound claimed in the instant application (pg. 4, L.10-11), except that the Cameron PGE₂ lacks the 4,4 -difluoro substitution of the instantly claimed compound. Maruyama discloses agonists of the EP₄ subtype receptor nearly identical to the instantly claimed compound also useful in the prevention of bone loss (abstract), where the difference constitutes a carboxylic acid terminus to the alpha chain in place of the instantly claimed 1*H*-tetrazol-5-yl group. (Pg. 14). The differences between the claimed compound and that disclosed in Cameron and Murayama represent straightforward cases of bioisosterism (Camille Wermuth, *Molecular Variations Based on Isosteric Replacements*, THE PRACTICE OF MEDICINAL CHEMISTRY 204 (1996)), moreover when considered in light of the comparable uses (replacement of bone loss) both compounds are disclosed as capable of. This concomitance of use indicates a comparable physiological effect the comparable structures share, and in light of the evidence provided that either acts as a potent EP₄ subtype receptor agonist, would have been obvious to one of skill in the art at the time of the invention that a combination of the disclosed structures would highly probably result in a compound of potent EP₄ subtype receptor agonism as well.
13. Claims 20, 22, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cameron and Maruyama as applied to Claims 17-19, 21, 24, and 26 above, and further in view of

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International Application Publication WO00/38667 (hereinafter Klimko”), and U.S. Patent 6,344,477 (hereinafter “Sharif”). While Cameron and Maruyama describe compounds as provided above, they do not indicate compositions comprising the instant claimed compound in combination with additional compounds for the treatment of ocular diseases. Klimko describes the use of EP receptor agonists in combination with beta-blockers in the reduction of intraocular pressure and the treatment of glaucoma. (Pg. 4). Sharif indicates that EP₄ subtype receptor agonists are useful in the treatment of dry eye type disorders. (C.4, L.60-65). Because Cameron and Murayama disclose bioisosteres of the instant claimed EP₄ subtype receptor agonist, it would have been prima facie obvious to combine their teachings to arrive at an instant claimed EP₄ subtype receptor agonist capable of treatment of glaucoma in combination with beta blockers as described by Klimko, or treating dry eye disorders when combined with the teaching of Sharif.

Conclusion

No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SMB

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161